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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,263	07/15/2003	Olga Bandman	PF-0479-2 DIV	3333
22428	7590	02/28/2006	EXAMINER	
FOLEY AND LARDNER LLP			SANG, HONG	
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WASHINGTON, DC 20007			1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/621,263	Applicant(s) BANDMAN ET AL.	
	Examiner Hong Sang	Art Unit 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**RE: Bankman et al.**

Applicants' petition filed on 7/15/2003 to amend inventorship under 37 C.F.R. § 1.48(b) is acknowledged. The inventorship of the instant application is amended from that of:

Olga Bandman, Jennifer L. Hillman, Neil C. Corley, Karl J. Guegler, Mariah R. Baughn

To that of:

Olga Bandman, Neil C. Corley, Karl J. Guegler, Mariah R. Baughn.

This amendment has been entered.

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, 17, 18, and 56-58, drawn to an isolated polypeptide, a composition comprising a polypeptide, classified in class 530, subclass 350.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

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- II. Claims 3-7, 9, 10, 12, 13 and 59-61, drawn to an isolated polynucleotide, a cell, and a method of producing a polypeptide, classified in class 536, subclass 23.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species. This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

- III. Claim 8, drawn to a transgenic organism, classified in class 800, subclass 8.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species. This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

- IV. Claims 11, 31, 32, 34, 37, 38, and 40-43, drawn to an isolated antibody, a composition comprising an antibody, classified in class 530, subclass 387.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- V. Claims 14-16, drawn to a method of detecting a target polynucleotide in a sample, classified in class 435, subclass 6:

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species.  
This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

- VI. Claim 19, drawn to a method of treating a disease or condition comprising administering the composition comprising a polypeptide, classified in class 514, subclass 2.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species.  
This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- VII. Claims 20 and 23, drawn to a method of screening a compound for effectiveness as an agonist of a polypeptide of claim 1, a method of screening a compound for effectiveness as an antagonist of a polypeptide of claim 1, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- VIII. Claim 21, drawn to a composition comprising an agonist compound of a polypeptide of claim 1, classified in class 530, subclass 300, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- IX. Claim 22, drawn to a method for treating a disease or condition comprising administering a composition comprising an agonist compound of a polypeptide of claim 1, classified in class 514, subclass 2.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

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- X. Claim 24, drawn to a composition comprising an antagonist compound of a polypeptide of claim 1, classified in class 530, subclass 387.1, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- XI. Claim 25, drawn to a method for treating a disease or condition comprising administering a composition comprising an antagonist compound of a polypeptide of claim 1, classified in class 424, subclass 130.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- XII. Claim 26, drawn to a method of screening for a compound that specifically binds to the polypeptide of claim 1, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- XIII. Claim 27, drawn to a method of screening for a compound that modulates the activity of the polypeptide of claim 1, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species.  
This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- XIV. Claim 28, drawn to a method of screening for a compound for effectiveness in altering expression of a target polynucleotide of claim 5, classified in class 435, subclass 6.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species.  
This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

- XV. Claim 29, drawn to a method of assessing toxicity of a test compound, classified in class 435, subclass 4.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID



NOS. 4-6. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

- XVI. Claims 30, 33, 35, and 44, drawn to a method for diagnostic test for a condition or disease associated with the expression of HPRM in a biological sample using an antibody of claim 11, or a composition comprising an antibody, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID

NOS. 1-3. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

- XVII. Claim 36, drawn to a method of preparing a polyclonal antibody with the specificity of the antibody of claim 11, classified in class 435, subclass 69.6, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID

NOS. 1-3. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

XVIII. Claim 39, drawn to a method of making a monoclonal antibody with the specificity of the antibody of claim 11, classified in class 435, subclass 70.21.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

XIX. Claim 45, drawn to a method of purifying a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO. 1-3 using an antibody, classified in class 530, subclass 412, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 1-3. This election should not be construed as an election of species. This is a restriction requirement. Each of the polypeptides is structurally and functionally distinct molecule that would require separate search.

XX. Claims 46 and 48-55, drawn to a microarray, classified in class 536, subclass 24.3, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species.

This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

XXI. Claim 47, drawn to a method of generating an expression profile of a sample which contains polynucleotides, classified in class 435, subclass 6, for example.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single SEQ ID NO from SEQ ID NOS. 4-6. This election should not be construed as an election of species.  
This is a restriction requirement. Each of the polynucleotides is structurally and functionally distinct molecule that would require separate search.

2. The inventions are distinct, each from the other because of the following reasons:

The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While a polypeptide of group I can be made using the polynucleotides of group II, the polypeptide can also be made by another and materially different process, such as by peptide synthesis or purification from the natural source. Further, the polynucleotide may be used for the processes other than the production of the protein, such as nucleic acid hybridization. For these reasons, the inventions of

groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. Furthermore, a search of the nucleic acid molecules of group II would also requires an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group I. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group I and the antibody of group IV are patentably distinct for the following reasons:

While the inventions of both group I and group IV are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions,

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and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group IV are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. While the polypeptide of group I can be used to make antibodies of group IV, the polypeptide of group I can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein

Furthermore, searching the inventions of group I and group IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group IV. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group II and the antibody of group IV are patentably distinct for the following reasons. The antibody of group IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group IV which are composed of amino acids, and polynucleotides of group II, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group IV, and the antibody of group IV cannot be encoded by a polynucleotide of group II. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group II and group IV would impose a serious search burden since a search of the polynucleotide of group II is would not be used to determine the patentability of an antibody of group IV, and vice-versa.

Groups III, VIII, X, XX and any one of groups I, II, and IV are distinct because a transgenic organism, an agonist of a polypeptide, an antagonist of a polypeptide, a microarray, a polypeptide, and an antibody are all structurally and functionally distinct.

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Moreover they have separate status in the art, therefore searching them together would impose a serious burden.

Group I and any one of groups VI, VII, XII, XIII, and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used to diagnose a disease as opposed to being used for treating a disease or screening a compound.

Searching the inventions of Group I and any one of groups VI, VII, XII, XIII and XVII together would impose serious search burden. The inventions of group I and groups VI, VII, XII, XIII and XVII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the methods of screening a compound, treating a disease or making a polyclonal antibody are not coextensive. Groups VI, VII, XII, XIII and XVII encompass molecules which are claimed in terms of antagonist, agonist, antibody, a subject to be treated, which are not required for the search of group I. Moreover, the search for groups VI, VII, XII, XIII and XVII would require a text search for the methods. Prior art which teaches a polypeptide would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Group II and any one of groups XIV and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used to make proteins as opposed to being used for screening a compound or assessing toxicity of a test compound.

Searching group II and any one of groups XIV and XV together would impose serious search burden. The inventions of group II and groups XIV and XV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the methods of screening a compound, and assessing toxicity of a test compound are not coextensive. Groups XIV and XV encompass hybridization assay, which are not required for the search of group II. Moreover, the search for groups XIV and XV would require a text search for the methods. Prior art which teaches a polynucleotide would not necessarily be applicable to the method of using the polynucleotide. Moreover, even if the polynucleotide product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.



Group IV and any one of groups XVI and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to treat a disease as opposed to being used for diagnose a disease or purifying a polypeptide.

Searching group IV and any one of groups XVI and XIX together would impose serious search burden. The inventions of group IV and groups XVI and XIX have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the methods for diagnostic a condition or a disease, and purifying a polypeptide are not coextensive. Groups XVI and XIX encompass method steps, which are not required for the search of group IV. Prior art which teaches an antibody would not necessarily be applicable to the method of using the antibody. Moreover, even if the antibody products were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Group IV and any one of groups XVII and XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and

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materially different process (MPEP § 806.05(f)). In the instant case the antibody can be made by recombinant technology or isolation from natural source as opposed to being made by immunizing an animal.

Searching group IV and any one of groups XVII and XVIII together would impose serious search burden. The inventions of group IV and groups XVII and XVIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the methods of making an antibody are not coextensive. Groups XVI and XIX encompass immunizing an animal, isolating an antibody, which are not required for the search of group IV. Prior art which teaches an antibody would not necessarily be applicable to the method of making the antibody. Moreover, even if the antibody products were known, the method of making the product may be novel and unobvious in view of the preamble or active steps.

Groups XX and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, a microarray can be used to diagnose a disease as opposed to being used for quantifying the expression of the polynucleotides in a sample.

Searching groups XX and XXI together would impose serious search burden. The inventions of groups XX and XXI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the

microarray and the methods of using a microarray are not coextensive. Group XXI encompass labeled polynucleotides and a sample, which are not required for the search of group XX. Prior art which teaches a microarray would not necessarily be applicable to the method of quantifying the expression of the polynucleotides in the sample. Moreover, even if the microarray was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions V-VII, IX, XI-XIX and XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of detecting a target polynucleotide in a sample (group V), the method of treating a disease or condition using a polypeptide (group VI), a method of screening a compound (group VII), a method for treating a disease or condition using agonist of the polypeptide (group IX), a method of treating a disease or condition using an antagonist of the polypeptide (group XI), a method of screening a compound that specifically binds to the polypeptide (group XII), a method of screening for a compound that modulates the activity of the polypeptide (group XIII), a method of screening for a compound altering expression of the polynucleotide (group XIV), a method of assessing toxicity of a test compound (group XV), a method for diagnostic test for a condition or disease using an antibody (group XVI), a method of preparing a polyclonal antibody (group XVII), a method of preparing a polyclonal antibody (group XVIII), a method of purifying a polypeptide (group XIX), and a method of generating an

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expression profile of a sample using a microarray (group XXI) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. For group V, a polynucleotide is detected by hybridization assay or PCR, for group VI, a polypeptide is used to treat a disease, for group VII, the activity of agonist or antagonist is measured, for group IX, an agonist of the polypeptide is used to treat a disease, for group XI, an antagonist is used to treat a disease, for group XII, the binding between a test compound and polypeptide is measured, for group XIII, the activity of polypeptide is measured in the presence or absence of a test compound, for group XIV, the expression of a polynucleotide is measured in the presence or absence of a test compound, for group XV, the amount of hybridization complex is measured to assessing toxicity of a test compound, for group XVI, an antibody is used to diagnose a disease, for group XVII, a polyclonal antibody is made by immunizing an animal, for group XVIII, hybridoma cells are used to generate monoclonal antibody, for group XIX, an antibody is used to purify a polypeptide, and for group XXI, an microarray is used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions V-VII, IX, XI-XIX and XXI are patentably distinct.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other, searching them together would impose serious burden.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re*

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Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145.

The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang  
Art Unit: 1643  
Dec. 21, 2005



LARRY R. HELMS, PH.D.  
SUPERVISORY PATENT EXAMINER